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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,526	02/10/2000	Kuanghui Lu	CIBT-P01-058	1398

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

21

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/499,526

Applicant(s)

LU ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 November 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 13, 15-23, 28-33, 39, 45, 46, 50, 51, 53, 57-60, 63, 76-78, 85.Claim(s) withdrawn from consideration: 1-12, 24-27, 34-38, 40-44, 47-49, 52, 55, 56, 61, 62, 64-75, 79-84 and 86.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: amended claim 28 is an improper Markush group.

Continuation of 5. does NOT place the application in condition for allowance because: claims 13-23, 28-33, 39,45,46,50,51,53,54,57-60, 63,76-78,85 stand rejected under 35 USC 112, first paragraph scope of enablement. The rejections are maintained for reason of record. Applicant has stated that they point to patent 5,574,010 not to demonstrate enablement of the treatment per se, but rather demonstrate that many PYY agonists were known to one skilled in the art at the time of filing of the present application, and that any of these would be efficacious in the claimed method. This is not found persuasive because the methods in patent 5,574,010 are drawn to methods of treating pancreatic tumors using PYY and analogs of PYY. The instant claims are drawn to methods of altering glucose responsiveness comprising administering PYY agonist. No previously known PYY agonists were known to have the activity required in the instant claims. A PYY agonist used for treating pancreatic tumors would not necessarily have to the same activity as altering glucose responsiveness. PYY is a pleiotropic hormone. Analogs of PYY would have structure changes which could disrupt certain activities while maintaining others. Applicant's submission of abstracts (Bertrand et al., Bottcher et al.) teach that PYY inhibits insulin secretion stimulated by glucose. This is opposite the activity disclosed in the instant application, thus demonstrating the pleiotropic activity of PYY. Applicant states that the use of "PYY agonists" is fully enabled by the present specification and the level of skill in the art at the time of filing of the present application. This is not found persuasive. Applicant gives a definition of agonist (pg 14, lines 4-19). Agonist encompasses many agents (proteins, antibodies, compounds, etc) which differ structurally. Applicant is not enabled for the scope of this term. Applicant's submission of abstract Litvak and Liu demonstrate that the PYY agonists used were chemical compounds which differ structurally from PYY. Furthermore, Litvak and Balasubramaniam were published post-filing date of the instant application and cannot be considered. Therefore, Applicant has failed to overcome the 35 USC 112, first paragraph scope of enablement rejection.

Claims 13,15-23,28-33,39,45,46,50,51,53,54,57-60,63,76,-78,85 stand rejected under 35 USC 112, second paragraph. The rejections are maintained for reason of record. Applicant has replaced "PYY Therapeutic" with "PYY agonist". Applicant states that although the structure is not specified in the claims, the function is thus clarified sufficiently for one skill in the art to recognize the scope of the term. This is not found to be persuasive because the structural metes and bounds of the term "PYY agonist" cannot be determined.